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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/626,966

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William G. Dennis

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/626,966	Applicant(s) DENNIS, WILLIAM G.	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,32,34-43,45-53,55,56 and 69-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,32,34-43,45-53,55,56 and 69-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action replaces the Office actions mailed out on 3/3/10 and 3/23/10.
2. Claims 31, 32, 34-43, 45-53, 55, 56, and 69-72 are pending in this present application and they are presented for examination.
3. This Office action is in response to the amendment filed on October 20, 2009.

Response to Amendment and Arguments

4. According to the amendment, independent claims 31 and 42 have been amended to correct the insufficient antecedence basis, therefore, the objection to claims 31, 42 and its dependent claims in previous Office action has been withdrawn.
5. Paragraph [0053] has been amended to correct minor informalities, therefore, the objection to the specification in previous Office action has been withdrawn.
6. Applicant's arguments have been fully considered but they are not persuasive for the reasons set forth below.
 - a. argues that Shipp fails to disclose new limitation of "the applicator ~~adopts~~ applies a first ~~stage~~ force in which the jaw push tube advances and causes the jaws to engage but the clip pusher does not move, and a second, later, ~~stage~~ force discontinuous to the first force in which the clip pusher advances to urge a clip onto the support shelves of the engaged jaws" as required in claims 31 and 42 is incorrect. Shipp discloses (col. 11, lines 35-50) "Also as the actuator lever 184 pivots clockwise from the

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initial position of FIG. 2 the lever 184 pushes against piston 114 forward within the bore 132...when trigger 16 is squeezed and actuator lever 184 begins to pivot, force is immediately simultaneously applied to begin closing the jaws and to begin pushing the clips. There is a slight delay in the beginning of movement of the clips due to the compression of spring 125". Examiner contends that "slight delay" is equivalent to the limitation of "discontinuous" as required in claims 31 and 42.

- b. With respect to the argument that "there are two discrete stage/forces being applied in the present claimed invention" to the contrary as admitted by the Examiner, SHIPP's steps are continuous. Examiner respectfully traverses applicant's remarks. Examiner contends that clip applicator as disclosed by Shipp has two discrete stage/forces. Shipp discloses the rear portion of pusher rod piston 114 is engaged with spring 125 (col. 9, lines 38-40 and Figs. 2 and 4). When the trigger 16 is squeezed the actuator lever 184 begins to pivot, force is immediately applied to the primary outer tube piston 164 to slide forward to begin closing the jaws 20 and 22 (Figs. 2 and 4 and col. 10, line 55 to col. 11, line 5), which is interpreted as the first stage/force, then force applied on the trigger 16 is continued to increase to compress the spring 125, after some compression of spring 125 the movement of clips in the magazine 58 is begin, which is interpreted as the second stage/force (col. 11, lines 40-45).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 31 and its dependent claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. New limitation of “a second, later, force discontinuous to the first force”, especially “discontinuous” is new matter. Turning to specification for guidance, one finds, paragraph [0074] discloses “the triggered actions of the applicator 20 appear to be simultaneous. The user places the open jaws 261, 262 over the portion of the fallopian tube to be occluded and squeezes the trigger 211 to its fullest extend in one continuous motion”. The limitation of “**squeezes the trigger 211 to its fullest extend in one continuous motion**” recited in paragraph [0074] describes the first force and the second force are not discontinuous. Paragraph [0069] of the present application discloses “the force applied to the sub-actuator 215 by the main actuator link 214 is increased”. It is appeared that applicant intended to claim “a second, later, force larger than the first force”.
8. Claims 42 and its dependent claims are rejected for the same reason as claim 31.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 31, 32, 34-43, 45-53, 55, 56, and 69-72 are rejected under 35**

U.S.C. 102(b) as being anticipated by Shipp et al. (U.S. 6,350,269).

11. Referring to claim 31, Shipp discloses (see Figs. 1-9 and 13-34) an occlusion clip applicator 10 for storing and applying a plurality of occlusion clips 64 (see Fig. 9), the applicator comprising:

- a. a jaw push tube 18 having proximal and distal push tube ends and a jaw push tube interior;
- b. an elongate clip holder 58 (see Figs. 13-18 and col. 6, lines 49-63) configured to hold the plurality of occlusion clips, the clip holder being formed as a channel having first and second support rails 61 and 63 attached thereto, the first and second support rails being substantially parallel and in alignment with each other and defining a gap with a gap width dimension that is greater than the main body width of the occlusion clips 64 and less than the maximum arcuate width 72 (see Fig. 9) of the occlusion clips, the clip holder having proximal and distal clip holder ends and being disposed inside the jaw push tube interior;

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- c. a clip pusher 102 (see Figs. 25-28 and see col. 9, lines 23-55) having an elongate support member having upper and lower sides with a plurality of clip push prong 104 or fingers 104 attached to the lower side wherein the finger 104 configured to engage the upper arcuate portions 72, 74 of the occlusion clips 64 so that distal movement of the clip pusher causes the occlusion clips to slide distally along the support rails 61, 63, the support member 102 being mounted within the jaw push tube interior substantially parallel to the clip holder 58 with at least a portion of each clip push finger extending downward into the channel;
- d. a pair of jaws 20, 22, (see Fig. 19-24 and see col. 6, lines 37-49) each jaw having proximal and distal jaw ends, an inner engaging side and an opposite outer side, a clip slot 94 formed through the jaw from the inner engaging side to the outer side and extending distally from and through the proximal jaw end, and a pair of parallel support shelves 214, 216 bounding at least a portion of the clip slot, the jaws being pivotably mounted at their proximal ends 97 to the distal clip holder end 99 (see Figs. 18 and 19) and being configured for engagement by the distal tube end at 109, 111 for selective rotation between a fully open position and a closed position wherein the engaging sides of the jaws are in contact with each other, wherein the clip slot has a width dimension that is greater than the main body width of the occlusion clips and less than the maximum arcuate width of the occlusion clips; an releasing opening 96, 98 or

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ejection opening at the distal jaw end, wherein the ejection opening having a width that is greater than the maximum arcuate 72 of the occlusion clip 64;

- e. a trigger 16 associated or connected to actuator assembly, which includes actuator lever 184, primary outer tube piston 164, push rod piston 114 and intermediate outer tube 38. The trigger actuates the actuator assembly to actuate jaw push tube 18 to actuate the jaw 20, 22 open or close and moving clip pusher 102 to move a clip into the jaw 20, 22 (see col. 11, line 14 to col. 12, line 15). In column 11, lines 45-50 Shipp discloses when trigger 16 is squeezed and actuator lever 184 begins to pivot, force is immediately simultaneously applied to begin closing the jaws and to begin pushing the clips and there is a slight delay in the beginning of movement of the clips due to the compression of spring 125. Examiner contends that "slight delay" is equivalent to the limitation of "discontinuous" as required in claims 31 and 42. Further, Shipp discloses the rear portion of pusher rod piston 114 is engaged with spring 125 (col. 9, lines 38-40 and Figs. 2 and 4). When the trigger 16 is squeezed the actuator lever 184 begins to pivot, force is immediately applied to the primary outer tube piston 164 to slide forward to begin closing the jaws 20 and 22 (Figs. 2 and 4 and col. 10, line 55 to col. 11, line 5), which is interpreted as the first stage/force, then force applied on the trigger 16 is continued to increase to compress the spring 125, after some compression of spring 125 the movement of

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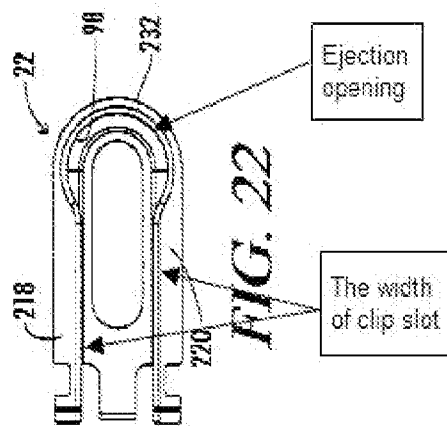
clips in the magazine 58 is begin, which is interpreted as the second stage/force (col. 11, lines 40-45).

- f. a handle assembly 12 and 16 include a barrel rotator 14 or a tube housing defining a bore 24 or a tube chamber (see col. 9, lines 57-60), the proximal push tube end of tube 18, the proximal clip holder end of clip holder 58 and at least a portion of the actuator assembly, which includes actuator lever 184, primary outer tube piston 164, push rod piston 114 and intermediate outer tube 38, to actuate jaw push tube 18 to actuate the jaw 20, 22 open or close and moving a clip into the jaw 20, 22 being disposed in the tube chamber (see col. 11, line 14 to col. 12, line 15).
12. Referring to **claims 34 and 55**, see item (b) in paragraph 11 above.
13. Referring to **claims 35, 45 and 56**, see item (c) in paragraph 11 above.
14. Referring to **claims 36-38, 40, 48 and 50**, Examiner understood that applicant intended to invoke 35 USC § 112, sixth paragraph. Shipp discloses (Figs.1-5 and 29-32) a trigger 16 associated or connected to actuator assembly, which includes actuator lever 184, primary outer tube piston 164, push rod piston 114 and intermediate outer tube 38. The trigger actuates the actuator assembly to actuate jaw push tube 18 to actuate the jaw 20, 22 open or close and moving clip pusher 102 to move a clip into the jaw 20, 22 (see col. 11, line 14 to col. 12, line 15).
15. Referring to **claims 39 and 49**, in column 11, lines 45-50, Shipp discloses when trigger 16 is squeezed and actuator lever 184 begins to pivot, force is immediately simultaneously applied to begin closing the jaws and to begin pushing the clips

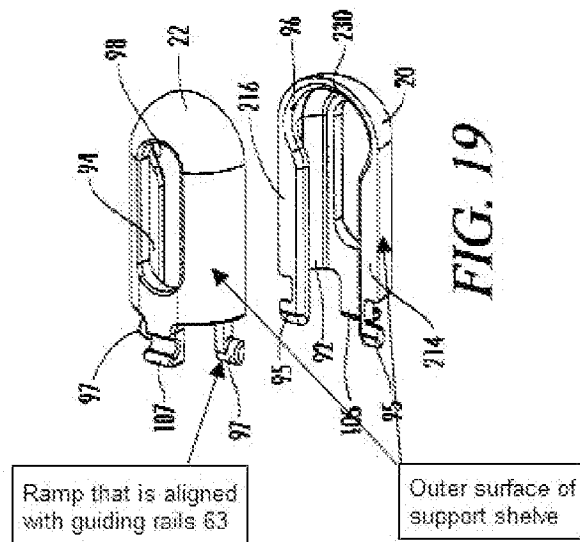
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and there is a slight delay in the beginning of movement of the clips due to the compression of spring 125. Thus, Shipp discloses the distal movement of the jaw push tube 18 and the clip pusher 102 happened in sequence initiated by a user via squeezing of the trigger 16.

16. Referring to **claims 41 and 51**, see item (f) in paragraph 11 above.
17. Referring to **claim 42**, with respect to the preamble, it has been carefully considered but deemed not to impose any structural limitation on the claims distinguishable over the applicator as disclosed by Shipp which is capable of being used to delivering the clip as recited in the preamble. Figures 8-12 of Shipp's drawings disclosed the clip that claimed in the preamble of claim 42. Further, in US Pub. No. 2006/0129168, Shipp discloses such a clip as claimed in the preamble of claim 42 (see Fig. 1), furthermore, Shipp discloses the clip can be deployed by a clip applicator as discloses in US Patent No. 6,350,269 issued to Shipp (see paragraph [0043]).
18. Referring to **claims 32 and 53**, Figure 22 (reproduced and annotated below) shows the jaw has a clip slot terminates in an ejection opening 98 adjacent the distal jaw end 232, the clip slot having a slot width and the ejection opening having an ejection opening width that is greater than the slot width.



19. Referring to **claims 71 and 72**, Figure 19 of Shipp's drawings shows jaw 22 includes a pair of ramps 97 for connecting the jaw to the distal end 101 of clip holder 58, wherein each ramp includes outer surfaces that aligned with the respective support rails 61 and 63 of the clip holder 58 (see Figs. 15 and 16) and are continuous with the outer surfaces of the respective support shelves (see Fig. 22 reproduced and annotated below).



Allowable Subject Matter

20. Claims 71 and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and amended as follow.

71. (Currently amended) An occlusion clip applicator according to claim 31, wherein each jaw further has a pair of ramps bounding a proximal portion of the clip slot, each ramp having a proximal end, wherein the proximal ends of the ramps having outer surfaces that match and are aligned with the respective support rails of the clip holder and are continuous with the outer surfaces of the respective support shelves.

72. (Currently amended) An occlusion clip applicator according to claim 42, wherein each jaw further has a pair of ramps bounding a proximal portion of the clip slot, each ramp having a proximal end, wherein the proximal ends of the ramps having outer surfaces that match and are aligned with the respective support rails of the clip holder and are continuous with the outer surfaces of the respective support shelves.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/TUAN V NGUYEN/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
5/7/10